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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

September 22, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2953242

John Byrnes
President
Lincare, Inc.
19337 U.S. 19 North, Suite 500
Clearwater, Florida 33764

Dear Mr. Byrnes:

During an inspection of your firm, Lincare, Inc., located at 5701 W. Charleston Blvd., Suite 105, Las Vegas, Nevada 89102, on September 11, 1998, FDA Investigator Paul A. Peterson documented deviations from the Current Good Manufacturing Practice Regulations as outlined in Title 21, Code of Federal Regulations, Parts 210 and 211, in conjunction with the repacking of Oxygen, USP. These deviations cause the drug to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act, as follows:

1. Failure to assay the incoming liquid oxygen for identity and strength prior to filling the liquid home units [21 CFR 211.165 (a)].

2. Failure to have adequately trained personnel to perform and supervise the operation [21 CFR 211.25].

3. Failure of batch production and control records to include identification of the persons performing and directly supervising or checking each significant step in the operation [21 CFR 211.188(b)(11)].

This letter is not intended to be an all inclusive list of violations. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. This warning letter will serve as official notification to management that FDA expects all your locations to be in compliance.

At the conclusion of the inspection, FDA 483, Inspectional Observations, was issued to and discussed with Ronald L. Schultz, Senior Service Representative. A copy is enclosed for your reference.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify this office within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within this time limit, state the reason for the delay and the time needed to complete the corrections.

Your reply should be sent to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070, attention: Steven R. Gillenwater, Medical Gas Monitor.

Enclosed are copies of the Current Good Manufacturing Practice Regulations (21 CFR 210 and 211); the Compressed Medical Gases Guideline; and "Fresh Air '98, A Look at FDA's Medical Gas Requirements," a speech by Duane S. Sylvia of the FDA's Center for Drug Evaluation and Research. The Compressed Medical Gases Guideline and Mr. Sylvia's speech contain useful information on how to comply with the regulations.

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District